

THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Ning Hu et al.

Title: METHOD OF DRUG LOADING IN LIPOSOMES BY GRADIENT

Docket No.: 1992.007US1

Serial No.: 10/723,431

Filed: November 26, 2003

Due Date: N/A

Examiner: Unknown

Group Art Unit: 1615

**Mail Stop Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ A return postcard.
- ☒ A Communication Concerning Related Applications (1 pg.).
- ☒ An Information Disclosure Statement (2 pgs.), Form 1449 (4 pgs.), and copies of 41 cited documents.
- ☒ Copy of International Search Report from Corresponding Foreign Application No. PCT/US 03/37964 (11 pgs.).

Please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

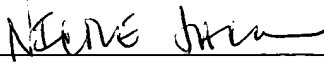
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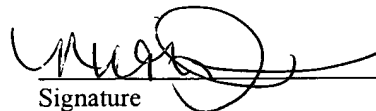
By: 

Atty: Gary J. Speier

Reg. No. 45,458

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)

S/N 10/723,431

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ning Hu et al.

Examiner: Unknown

Serial No.: 10/723,431

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COMMUNICATION CONCERNING RELATED APPLICATIONS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Applicants would like to bring to the Examiner's attention the following related applications in the above-identified patent application:

<u>Serial/Patent No.</u>	<u>Filing Date</u>	<u>Attorney Docket</u>	<u>Title</u>
10/723,423	November 26, 2003	1992.005US1	LIPOSOMAL FORMULATIONS

Respectfully submitted,

NING HU ET AL.

By Applicants' Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 359-3261

Date

2/7/05

By

Gary J. Speier

Reg. No. 45,458

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Name

Ning Hu

Signature

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S/N 10/723,431

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ning Hu et al.

Examiner: Unknown

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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

INFORMATION DISCLOSURE STATEMENT

Serial No :10/723,431

Filing Date: November 26, 2003

Title: METHOD OF DRUG LOADING IN LIPOSOMES BY GRADIENT

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).


Respectfully submitted,  
NING HU ET AL.

By their Representatives,  
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 359-3261

Date

2/7/05

By



Gary J. Speier

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/723,431
<b>Filing Date</b>	November 26, 2003
<b>First Named Inventor</b>	Hu, Ning
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Unknown

Sheet 1 of 4

Attorney Docket No: 1992.007US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date if Appropriate
	US-3,993,754	11/23/1976	Rahman, Yueh-Erh , et al.	10/09/1974
	US-4,145,410	03/20/1979	Sears, Barry D.	06/17/1997
	US-4,224,179	09/23/1980	Schneider, Michel	09/23/1980
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T <sup>2</sup>
	EP-0290296A2	11/09/1988	Bally, M. B., et al.	
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	WO-9913816A2	03/25/1999	Moynihan, Karen L., et al.	

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		"International Search Report, for Application No. PCT/US 03/37964, date mailed July 5, 2004", 11 Pages	
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**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

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(Use as many sheets as necessary)

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<b>First Named Inventor</b>	Hu, Ning
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Unknown

Sheet 2 of 4

Attorney Docket No: 1992.007US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BANDAK, S., et al., "Pharmacological studies of cisplatin encapsulated in long-circulating liposomes in mouse tumor models", <u>Anticancer Drugs</u> , 10, (November 10, 1999),911-920	
		BANGHAM, A D., "Diffusion of univalent ions across the lamellae of swollen phospholipids", <u>Journal of Molecular Biology</u> , 13(1), (August 1965),238-52	
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		HONG, R L., et al., "Direct comparison of liposomal doxorubicin with or without polyethylene glycol coating in C-26 tumor-bearing mice is surface coating with polyethylene glycol beneficial?", <u>Clinical Cancer Research</u> , 5(11), (November 1999),3645-3652	
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Substitute Disclosure Statement Form (PTO-1449)

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		ROSA, P. , et al., "Liposomes containg Doxorubicin - an example of drug targeting", In: <u>Transport in biomembranes : model systems and reconstitution</u> edited by Rezo Antolini, New York : Raven Press,(1982),243-256	
		RYMAN, BRENDA E., et al., "Liposomes: Further Considerations of their possible role as carriers of therapeutic agents", In: <u>Targeting of drugs</u> edited by Gregory Gregoriadis, New York : Plenum Press,(1982),235-248	
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		VEAL, G. J., et al., "A phase I study in paediatric patients to evaluate the safety and pharmacokinetics of SPI-77, a liposome encapsulated formulation of cisplatin", <u>British Journal of Cancer</u> , 84(8), (April 2001),1029-1035	
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